UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,588	11/29/2001	Chen Xing Su	10209.353	6233

21999 7590 04/20/2004

KIRTON AND MCCONKIE
1800 EAGLE GATE TOWER
60 EAST SOUTH TEMPLE
P O BOX 45120
SALT LAKE CITY, UT 84145-0120

EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,588	SU ET AL.	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-28* is/are pending in the application.

4a) Of the above claim(s) *13-23,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/01/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 4-28 are pending in the application.

Claims 13-23 were withdrawn from further consideration on the merits as being drawn to a non-elected invention per the election without traverse in the Office Action dated 6/18/03. Claims 27 and 28 were also withdrawn from consideration as being drawn to a non-elected invention due to election by original presentation in the Office Action dated 2/1 1/03.

Claims 1 , 4-12 and 24-26 were presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1 and 9 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments were fully considered, but not found persuasive.

Applicants' principal argument resides in the contention that because the Specification teaches broadly that 'more than one ounce' of noni juice may be administered per day, that this limitation 'inherently' includes 'three ounces'. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads) MPEP §2163 [R-1] I. B.

Although Applicants disclosed 'more than one ounce' in the Instant specification, it is deemed that Applicants are not entitled to limitations which do not have specific support in the Specification. It is not entirely clear *what* Applicants contemplated to be 'more than one ounce' and therefore, it also cannot be clearly determined if Applicants intended the scope of 'more than one ounce' to include 'three ounces'. It is therefore determined that Applicants *did not contemplate the specific use of three ounces* of noni juice. An analogous situation would be one in which the Specification taught a seasoning for food, but a new amendment to a claim recited 'seasoning for fish'. If the

original Specification did not teach 'fish', there would be no basis to conclude that Applicants were actually in possession of, or even contemplated the use of the seasoning for fish. Accordingly, In the Instant case Applicants did not teach that 'three ounces' of noni juice was in any way crucial to the claimed invention. It is noted that this limitation is indeed crucial, since it is present in the body of the claim.

It is for the reasons set forth *supra,* that this rejection remains standing.

Claim Rejections - 35 USC § 103

Claims 1, 4-12, 24 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mumford (1998) in view of Brock et al. (1991), in view of Gagnon (1997) and further in view of Nahir (EP 0 555 573 A1).

Applicant's arguments were fully considered, but not found persuasive.

Applicant principally argues that none of the references teach 'consuming on an empty stomach each day to inhibit, prevent, and reverse lipid peroxidation, three ounces of a dietary supplement comprising *Morinda citrifolia* fruit juice'. It is noted that "The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the ***rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in***

the art, established scientific principles, or legal precedent established by prior case law" (emphasis added) (MPEP § 2114).

In the Instant case, as clearly taught by Gagnon, taking medicinal preparations on an empty stomach to increase the preparation's effectiveness was considered conventional knowledge (see previous Office Action). *Morinda citrifolia* was known in the art as a medicinal preparation. Therefore, the ordinary artisan would have had a reasonable expectation that if *Morinda citrifolia* were taken on an empty stomach, that the medicinal effectiveness would have increased. Further, although none of the references taught the importance of consuming three ounces of Noni juice a day, it is deemed that because *Morinda citrifolia* was known in the art for having some pharmaceutical benefits, the ordinary artisan would have had a reasonable expectation that the consumption of three ounces a day would have also had some beneficial effect. Varying quantities of known medicinal preparations is considered optimization of result effective variables, routine in the art of nutritive pharmacology.

Applicants argue that

"The present invention, on the other hand, seeks to reduce free radicals in the body, which are caused by oxygenation. Accordingly, the present invention teaches consuming a Morinda citrifolia containing supplement to reduce oxygenation and, hence, the production of free radicals. As the prior art teaches that reducing oxygenation exacerbates migraine headaches, one skilled in the art would not be motivated by Mumford to modify the invention disclosed therein .to inhibit,

reverse and prevent lipid peroxidation as claimed by the present invention since reducing oxygenation would vitiate the purpose of Mumford in reducing the frequency and severity of migraine headaches. It is noted again that the language in the claim which states 'to inhibit, prevent and reverse lipid peroxidation' is merely an intended use of the method for delivering the juice to the patient" (p. 4, Remarks).

It is deemed that the results of inhibiting, preventing and reversing lipid peroxidation would have occurred due to the ingestion of the juice, and is therefore considered an intrinsic property of the methods disclosed in the prior art especially lacking convincing evidence to the contrary. This is further evidenced by the fact that the Instant specification teaches that one ounce of noni juice will perform this function (see for example, original claim 1). Therefore, since Mumford taught that a person drank two ounces of noni juice per day, it is deemed that drinking the juice would have intrinsically manifested these effects.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A Patten
Examiner
Art Unit 1654

4/14/04

PATRICIA PATTEN
PATENT EXAMINER